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COVID-19

Safety of COVID-19 vaccines

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The European Medicines Agency (EMA) monitors the safety of COVID-19 vaccines authorised in the European Union (EU) extremely carefully. This enables the detection of any rare side effects that may emerge once many millions of people are vaccinated.

- Around 950 million doses of vaccines have been given to people in the EU and European Economic Area (EEA), as of mid November 2022.
- The authorised COVID-19 vaccines are safe and effective. They were evaluated in tens of thousands of participants in clinical trials and have met EMA's scientific standards for safety, efficacy and quality.
- The safety of COVID-19 vaccines is continuously monitored and evaluated.
- The vast majority of known side effects of COVID-19 vaccines are mild and short-lived.
- Serious safety problems are extremely rare.

Safety information

EMA published the final issue of its monthly safety update on COVID-19 vaccines in December 2022.

EMA's **monthly safety updates** provided information from the Pharmacovigilance Risk Assessment Committee (PRAC)'s assessment of COVID-19 vaccines, along with data on the number of doses administered in the EU/EEA.

In total, EMA published more than 50 monthly **COVID-19** vaccine safety updates, beginning in December 2020.

By December 2022, the majority of the EU population had received at least one COVID-19 vaccine.

The wide uptake of COVID-19 vaccines during the COVID-19 pandemic led to the rapid accumulation of extensive safety data from clinical trials, studies and spontaneous reporting on side effects. These data have established the **safety profiles** of these vaccines. Therefore, regular monthly safety updates are no longer necessary.

EMA continues to monitor and assess **safety data** on COVID-19 vaccines, as it does for all medicines authorised in the EU.

If PRAC recommends important safety-related changes to the product information of

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- European suspected adverse drug reactions database (www.adrreports.eu)
- Important information on how to interpret the data

Comirnaty

(BioNTech and Pfizer)

Status on 13/11/2022

701,000,000

Doses given to people in the EU/EEA, including over 16,000,000 doses of adapted vaccines

971,021*

Reports of suspected side effects in the EU/EEA, including 3,670 cases for adapted vaccines (see www.adrreports.eu)

* Reported cases concern suspected side effects, i.e. medical events that have been observed after vaccination, but which are not necessarily related to or caused by the vaccine.

Read latest safety update

All Comirnaty safety updates >

Vaxzevria

(AstraZeneca)

Status on 13/11/2022

69,000,000

Doses given to people in the EU/EEA

328,643*

Reports of suspected side effects in the EU/EEA (see www.adrreports.eu)

* Reported cases concern suspected side effects, i.e. medical events that have been observed after vaccination, but which are not necessarily related to or caused by the vaccine.

Read latest safety update

All Vaxzevria safety updates >

Spikevax

(Moderna)

Status on 13/11/2022

161,000,000

Doses given to people in the EU/EEA, including over 317,000 doses of adapted vaccines

273,947*

Reports of suspected side effects in the EU/EEA, including 3,120 cases for adapted vaccines (see www.adrreports.eu)

* Reported cases concern suspected side effects, i.e. medical events that have been observed after vaccination, but which are not necessarily related to or caused by the vaccine.

Read latest safety update

All Spikevax safety updates >

Jcovden

(Janssen)

Status on 13/11/2022

18,600,000

Doses given to people in the EU/EEA

58,223*

Reports of suspected side effects in the EU/EEA (see www.adrreports.eu)

* Reported cases concern suspected side effects, i.e. medical events that have been observed after vaccination, but which are not necessarily related to or caused by the vaccine.

Read latest safety update

All Jcovden safety updates >

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Status on 13/11/2022

361,000

Doses given to people in the EU/EEA

1,423*

Reports of suspected side effects in the EU/EEA (see www.adrreports.eu)

* Reported cases concern suspected side effects, i.e. medical events that have been observed after vaccination, but which are not necessarily related to or caused by the vaccine.

Read latest safety update

All Nuvaxovid safety updates

Status on 13/11/2022

2,900

Doses given to people in the EU/EEA

24*

Reports of suspected side effects in the EU/EEA (see www.adrreports.eu)

* Reported cases concern suspected side effects, i.e. medical events that have been observed after vaccination, but which are not necessarily related to or caused by the vaccine.

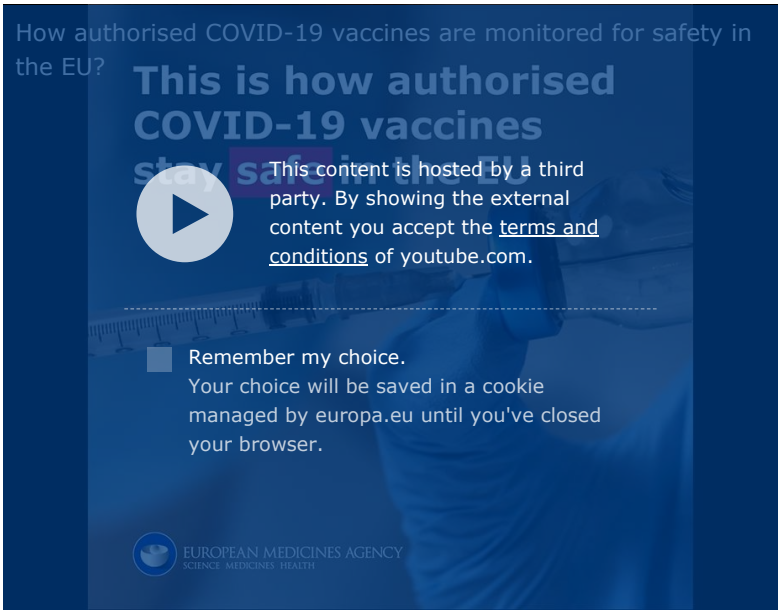
Read latest safety update

All COVID-19 Vaccine Valneva safety updates

How EMA monitors vaccine safety

The EU safety monitoring plan for COVID-19 vaccines requires EMA to monitor suspected side effects reported by individuals and healthcare professionals in the EU.

An EU database called EudraVigilance holds these reports. The European suspected adverse drug reactions database provides public access to these data in a number of ways, while taking account of EU data protection law.



EMA's PRAC and the national competent authorities continuously monitor EudraVigilance to identify any new safety issues that require investigation. These are known as **safety signals**.

When assessing a safety signal, the PRAC looks for any unusual or unexpected patterns, such as a medical event occurring in vaccinated people at a higher rate than in the general population.

They review other sources of evidence, such as clinical studies, epidemiology and pharmacoepidemiology studies, the medical literature and information from regulators outside the EU.

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If needed, EMA may decide to update the vaccine's product information to provide the right advice to healthcare professionals and patients, require the manufacturer to conduct additional studies, or restrict the use of the vaccine.

Patients and healthcare professionals should report any suspected side effects after receiving a COVID-19 vaccine to their national competent authority. For information on how to do this see:

- Reporting a suspected side effect

Related content

- COVID-19 vaccines: Monitoring vaccine safety and use in real life
- Monitoring of COVID-19 medicines

External links

- European suspected adverse drug reactions database
- European Vaccination Information Portal: Monitoring vaccine safety and reporting side effects
- European Commission: Safe COVID-19 vaccines for Europeans
- European Council: COVID-19: the EU's contribution to global vaccine solidarity
- European Centre for Disease Prevention and Control (ECDC): COVID-19 vaccine tracker

Topics

- COVID-19
- Pharmacovigilance
- Vaccines

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